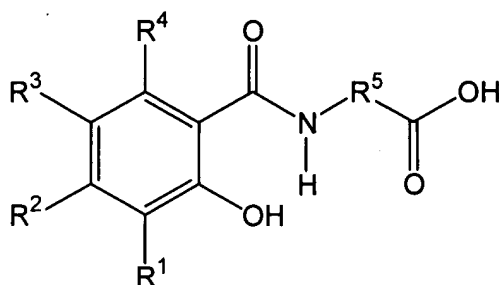


**IN THE CLAIMS:**

Claim 1 (Original): A disodium salt of a delivery agent having the formula



wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

Claim 2 (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

Claim 3 (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

Claim 4 (Original): The disodium salt of claim 1, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

Claim 5 (Original): An ethanol solvate of the disodium salt of claim 1.

Claim 6 (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

Claim 7 (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

Claim 8 (Original): The ethanol solvate of claim 5, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

Claim 9 (Original): A monohydrate of the disodium salt of claim 1.

Claim 10 (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

Claim 11 (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

Claim 12 (Original): The monohydrate of claim 9, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

Claim 13 (Original): A composition comprising at least about 50% by weight of the disodium salt of claim 1, based upon 100% total weight of delivery agent and salts thereof in the composition.

Claim 14 (Original): The composition of claim 13, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

Claim 15 (Original): A composition comprising:

- (a) the disodium salt of claim 1, ethanol solvate thereof, or monohydrate thereof; and
- (b) at least one active agent.

Claim 16 (Original): The composition of claim 15, wherein the composition comprises at least about 50% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

Claim 17 (Original): The composition of claim 16, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

Claim 18 (Original): The composition of claim 15, wherein the composition comprises at least about 90% by weight of the monohydrate, based upon 100% total weight of hydrate of the disodium salt of the delivery agent in the composition.

Claim 19 (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of growth hormones; human growth hormones; recombinant human growth hormones; bovine growth hormones; porcine growth hormones; growth hormone-releasing hormones; interferons;  $\alpha$ -interferon;  $\beta$ -interferon;  $\gamma$ -interferon; interleukin-1; interleukin-2; insulin; porcine insulin; bovine insulin; human insulin; human recombinant insulin; insulin-like growth factor; IGF-1; heparin; unfractionated heparin; heparinoids; dermatans; chondroitins; low molecular weight heparin; very low molecular weight heparin; ultra low molecular weight heparin; calcitonin; salmon calcitonin; eel calcitonin; human calcitonin; porcine calcitonin; erythropoietin; atrial natriuretic factor; antigens; monoclonal antibodies; somatostatin; protease inhibitors; adrenocorticotropin; gonadotropin releasing hormone; oxytocin; leutinizing-hormone-releasing-hormone; follicle stimulating hormone; glucocerebrosidase; thrombopoietin; filgrastim; prostaglandins; cyclosporin; vasopressin; cromolyn sodium; sodium chromoglycate; disodium chromoglycate; vancomycin; desferrioxamine; parathyroid hormone; fragments of parathyroid hormone; antimicrobials; anti-fungal agents; vitamins; analogs, fragments, mimetics and polyethylene glycol-modified derivatives of these compounds; and any combination thereof.

Claim 20 (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of heparin and calcitonin.

Claim 21 (Original): A dosage unit form comprising:

- (a) the composition of claim 15; and
- (b)
  - (i) an excipient,
  - (ii) a diluent,
  - (iii) a disintegrant,
  - (iv) a lubricant,
  - (v) a plasticizer,
  - (vi) a colorant,
  - (vii) a dosing vehicle, or
  - (viii) any combination thereof.

Claim 22 (Original): A solid dosage unit form comprising a lyophilized mixture comprising

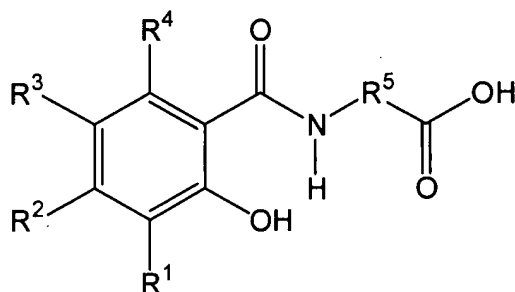
- (a) the disodium salt of claim 1; and
- (b) at least one active agent.

Claim 23 (Canceled)

Claim 24 (Original): A method for preparing a composition comprising mixing:

- (a) at least one member selected from the group consisting of the disodium salt of claim 1, ethanol solvates thereof, and monohydrates thereof;
- (b) at least one active agent; and
- (c) optionally, a dosing vehicle.

Claim 25 (Original): A method for preparing an anhydrous disodium salt of a delivery agent comprising drying the ethanol solvate of the disodium salt of the delivery agent, wherein the delivery agent has the formula



wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

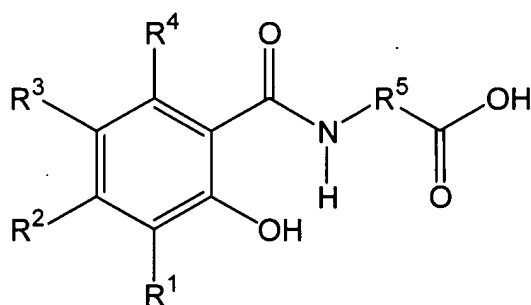
R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

Claim 26 (Original): A method of preparing an ethanol solvate of the disodium salt of a delivery agent comprising:

- (a) dissolving the delivery agent in ethanol to form a delivery agent/ethanol solution; and
- (b) reacting the delivery agent/ethanol solution with a molar excess of a sodium containing salt to form the ethanol solvate,

wherein the delivery agent has the formula



wherein

$R^1$ ,  $R^2$ ,  $R^3$ , and  $R^4$  are independently hydrogen, -OH,  $-NR^6R^7$ , halogen,  $C_1$ - $C_4$  alkyl, or  $C_1$ - $C_4$  alkoxy;

$R^5$  is a substituted or unsubstituted  $C_2$ - $C_{16}$  alkylene, substituted or unsubstituted  $C_2$ - $C_{16}$  alkenylene, substituted or unsubstituted  $C_1$ - $C_{12}$  alkyl(arylene), or substituted or unsubstituted aryl( $C_1$ - $C_{12}$  alkylene); and

$R^6$  and  $R^7$  are independently hydrogen, oxygen, or  $C_1$ - $C_4$  alkyl.

Claim 27 (Original): The method of claim 26, further comprising the step of:

(c) recovering the ethanol solvate from the solution containing the ethanol solvate formed in step (b).

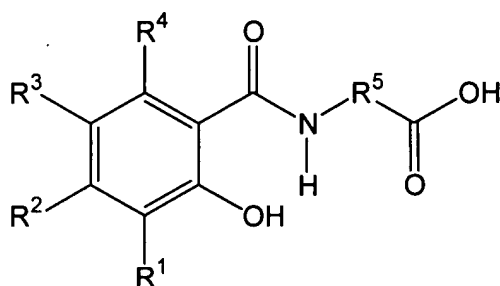
Claim 28 (Original): A method of preparing a monohydrate of a disodium salt of a delivery agent, the method comprising

(a) obtaining an ethanol solvate of the disodium salt of the delivery agent;

(b) drying the solvate to form an anhydrous disodium salt; and

(c) hydrating the anhydrous disodium salt to form the hydrate,

wherein the delivery agent has the formula



wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.



Claim 29 (New): A method for administering salmon calcitonin to an animal in need thereof, the method comprising administering orally to the animal a composition comprising:

(a) N-(5-chlorosalicyloyl)-8-aminocaprylic acid, wherein N-(5-chlorosalicyloyl)-8-aminocaprylic acid comprises at least about 96% by weight of the disodium salt of N-(5-chlorosalicyloyl)-8-aminocaprylic acid; and

b) salmon calcitonin.